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VIA ECF

Honorable Renee Marie Bumb, Chief Judge
United States District Court for the District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, New Jersey 08101

Re: *Corcept Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.*
Civil Action No.: 18-3632 (consolidated) (RMB) (LDW)

Dear Judge Bumb:

This firm, together with Sterne, Kessler, Goldstein & Fox, P.L.L.C., represents Defendant Teva in the above-referenced action. We write to draw the Court's attention to six hearsay declarations that were disclosed for the first time in this lawsuit as exhibits to Corcept's responsive post-trial brief, in an apparent attempt to compensate for the fact that the factual record developed during the more than five years that this case has been litigated reveals no instance of anyone practicing the methods claimed in the patents-in-suit.

After the close of evidence at trial, Your Honor advised the parties to focus their post-trial briefs, in part, on this issue: "what specific evidence is there in the record that the physicians will in the future infringe, specifically what evidence is there that physicians are co-administering a CYP3A with more than 300 milligrams" Tr. 493:17–21. The Court presumably thought the identification of such record evidence important, as Your Honor noted that "the evidence of the new drug, osilodrostat, and the evidence that the co-administration is only for the very seriously ill, and that the studies that were done on this did not involve the seriously ill patients, which seems, in this Court's mind, to suggest a huge disincentive, or at least a reluctance, to either, number one, co-administer at all, or, two, co-administer above the 300 milligrams." Tr. 493:21–494:4.

After reading the opening post-trial briefs, the Court issued a letter order noting that "Corcept has not pointed to record evidence of prior instances of co-administration at an infringing sequence or dosage" even though the Court had "invited this evidence during and after trial." Letter Order at 2, D.I. 292 (Nov. 2, 2023). Teva reasonably understood the Court's letter as giving Corcept one last chance to identify evidence *in the record* showing past instances of infringement. Teva did not understand the Court to be inviting Corcept to manufacture new evidence in the form of declarations from witnesses not mentioned in the final pretrial order, not deposed in the case, not

considered by any expert in the case, and not even identified in any of Corcept's Rule 26 disclosures. But that is what Corcept did.

Together with its five-page responsive post-trial brief, Corcept submitted six separate declarations from persons who assert, in a conclusory fashion, that they have co-administered mifepristone and a strong CYP3A inhibitor in an infringing manner. Notably, none of the declarants provides any detail about when, where, why, how often, to whom, to what effect, or with what other drugs the putative infringement was carried out.

By way of explanation for this untimely effort to present evidence of direct infringement that Corcept failed to adduce during the five-year pendency of this case, Corcept has the temerity to suggest that the Court actually *invited* Corcept to put in entirely new evidence together with its responsive post-trial brief. *See* Corcept's Responsive Post-Trial Brief at 5, D.I. 295 (Nov. 9, 2023) (requesting that the Court consider the newly minted physician declarations "in view of the Court's statement that it 'invited this evidence during *and after trial*' (D.I. 292)." (emphasis by Corcept)); *see also id.* at 5 n.3 ("in view of the Court's 'invit[ation],' Corcept respectfully submits this evidence now.")

In an attempt to justify its astonishing ambush of both Teva and the Court with new evidence in what should have been the very last filing in the case, Corcept cites three cases that are wholly inapposite. The first is a 50-year-old securities fraud case in which the Third Circuit articulated the rule that ought to control here: "[f]ailure to put into evidence all the proof necessary for sustaining a judgment is generally fatal." *Rochez Bros., Inc. v. Rhoades*, 527 F.2d 891, 894 (3d Cir. 1975). In *Rochez*, the Court of Appeals allowed for a narrow exception to that general rule to "insure substantial justice" because the defendant had been held liable for fraud (and the liability holding had already been affirmed on appeal), but some of the damages needed to be calculated based on the value of certain restricted stock shares that were difficult to value. *Id.* at 895. As the Court of Appeals put it, "[h]ere, injury has plainly been shown and liability has been conclusively established. Damages have been substantially determined with the exception of the [restricted] stock." *Id.* "What is not shown by the record is evidence pertaining to the restrictions on the stock and how the value is affected because of those restrictions." *Id.* Hence, the case was remanded to the district court "with instructions to take further testimony only regarding the correct discount factors that would apply to the [] restricted stock." *Id.* That very narrow exception has no applicability to the present case, where there has been no allegation of fraud, no conclusive determination of liability, no damages, and no remand from an appellate court with specific instructions to take additional evidence. *Rochez* provides no basis for departing from the general rule that parties need to put on their case during trial rather than afterwards.

Corcept's second cited case—a 20-year-old case about standing to sue under the Clean Water Act—again repeats the normal rule that "[f]ailure to adduce evidence adequate to sustain a judgment is generally fatal." *Natural Resources Defense Council, Inc. v. Texaco Refining and Marketing, Inc.*, 2 F.3d 493, 504 (3d Cir. 1993). On the unusual facts of that case, however, plaintiff NRDC's failure to put in evidence on one particular theory of standing was "due to a reasonable misunderstanding among the parties and the trial court." *Id.* Specifically, the district court had held in its opinion granting summary judgment that the NRDC had standing. When defendant Texaco argued that the NRDC should nevertheless have to prove standing at trial, the district court

confirmed that it had ruled on the issue “but then told Texaco’s counsel that after trial it could submit a proposed conclusion of law that plaintiffs lack standing if such a conclusion was warranted.” *Id.* At the end of trial, Texaco moved to dismiss on standing grounds, in particular due to lack of sufficient injury in fact. In response, the NRDC filed an affidavit stating that they believed only a different aspect of the standing inquiry would be revisited and that the summary judgment disposition had finally resolved the issue of injury in fact. *Id.* The district court agreed to reopen the record so that the NRDC could put in evidence about how its members were injured by Texaco’s polluting. *Id.* On appeal, the Third Circuit found no abuse of discretion in reopening the record because “the district court reasonably could have found that there was a legitimate misunderstanding concerning whether Texaco would be permitted to challenge plaintiff’s proof of injury in fact.” *Id.* In the present case, by contrast, Corcept does not and cannot argue that any prior ruling of this Court could be understood to have absolved Corcept of the need to prove a likelihood of direct infringement if Teva’s product is marketed.

Finally, Corcept cites an unpublished opinion by a magistrate judge from a different district, again involving a standing issue, for the proposition that one factor courts can consider in evaluating whether to reopen the record of a case is “whether the evidence sought to be introduced is especially important or probative.” *In re Chemed Corp., Shareholder Derivative Litigation*, No. 13-1854, 2017 WL 1712530 at *5 (D. Del. Apr. 25, 2017). True enough. But Corcept tellingly omits the other two factors mentioned in that same case: “the timing of the motion and the moving party’s explanation for failing to introduce the evidence earlier,” and “whether reopening will cause undue prejudice to the nonmoving party.” *Id.* Both of those factors weigh strongly against reopening the record in the present case. *See, e.g., Joy Techs., Inc. v. Flakt, Inc.*, 901 F. Supp. 180, 181–83 (D. Del. 1995) (applying same three-factor test and declining to reopen record in patent infringement case to admit new evidence discovered after trial and post-trial briefing).

Corcept’s gambit to supplement the record at the end of post-trial briefing is a tacit admission that Corcept failed to carry its burden to establish a likelihood of direct infringement. As Corcept’s own cited cases make clear, Corcept’s failure to adduce evidence adequate to sustain a judgment of infringement is fatal to its case.

Teva respectfully requests a telephone status conference to discuss Corcept’s belated submission and whether formal briefing and/or motion practice is necessary.

Respectfully submitted,

/s/ Liza M. Walsh

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cc: All Counsel of Record (via ECF and Email)